

**SPECIAL 510k****LIGAFIX® Interference screws****510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

MAR 29 2007

**1. GENERAL INFORMATION**

|                                    |                                                                                                                                                                                                                                                                                                                                |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trade Name                         | LIGAFIX® Resorbable Interference Screw                                                                                                                                                                                                                                                                                         |
| Common Name                        | Bone Fixation Screw                                                                                                                                                                                                                                                                                                            |
| Classification Name                | Screw, Fixation, Bone                                                                                                                                                                                                                                                                                                          |
| Class                              | II                                                                                                                                                                                                                                                                                                                             |
| Product Code                       | HWC                                                                                                                                                                                                                                                                                                                            |
| CFR section                        | 21CFR 888.3040                                                                                                                                                                                                                                                                                                                 |
| Device panel                       | Orthopedic                                                                                                                                                                                                                                                                                                                     |
| Legally marketed predicate devices | LIGAFIX® Resorbable Interference Screw K050407 and K061262                                                                                                                                                                                                                                                                     |
| Reason for special 510k            | Extension of the range of products                                                                                                                                                                                                                                                                                             |
| Submitter                          | SCIENCE FOR BIOMATERIALS<br>Sciences et Bio Matériaux<br>ZI du Monge<br>F 65100 LOURDES – FRANCE<br>Owner operation Number : 9063735                                                                                                                                                                                           |
| Contact                            | Denis CLEMENT, General Manager<br>Tel : +33 (0)5 62 42 21 01<br>Fax : +33 (0)5 62 42 21 00<br>e-mail : <a href="mailto:denis.clement@sbm-fr.com">denis.clement@sbm-fr.com</a><br><u>Regulatory contact:</u> Idée Consulting (FRANCE)<br>Isabelle DRUBAIX e-mail : <a href="mailto:idrubaix@nordnet.fr">idrubaix@nordnet.fr</a> |

**2. DEVICE DESCRIPTION**

LIGAFIX® are resorbable cannulated screws made of ceramic ( $\beta$ -TCP) / polymer (Poly Lactic Acid) composite and designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

To better fit the surgeon's needs and surgical preferences and patient's anatomy the full range of LIGAFIX Interference screws comprise:

- 2 material specifications: LIGAFIX® 30 (30% TCP/70% PLA) and LIGAFIX® 60 (60% TCP/40% PLA)
- 3 head design: standard – reduced – rounded
- Diameters from 7 mm to 11 mm
- Lengths from 20 mm to 35 mm

**SPECIAL 510k**  
**LIGAFIX® Interference screws**



LIGAFIX® interference screws are supplied sterile and individually packaged in double heat sealed pouches.

**3. INTENDED USE**

"LigaFix® interference screws are designed for the interference fixation of grafts in anterior cruciate ligament reconstruction."

**4. SUBSTANTIAL EQUIVALENCE**

The additional LIGAFIX® Interference screws have the same fundamental scientific technology, operating principle and intended use as previously cleared LIGAFIX® Interference screw K050407 and K061262.

Summary preparation date: February 13, 2007



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 29 2007

Science For Biomaterials  
% Mr. Denis Clement  
General Manager  
ZI du Monge  
F 65100 LOURDES, FRANCE

Re: K070507  
Trade/Device Name: Ligafix<sup>®</sup> Resorbable Interference Screw  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: February 16, 2007  
Received: February 27, 2007

Dear Mr. Clement:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

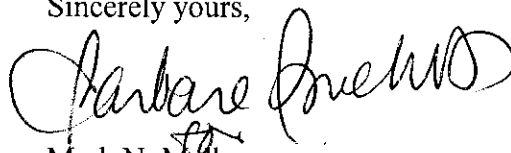
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Denis Clement

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use**

**510(k) Number (if known):** K070507

**Device Name: LIGAFIX® RESORBABLE INTERFERENCE SCREW**

**Indications for Use:**

"LigaFix® interference screws are designed for the interference fixation of grafts in anterior cruciate ligament reconstruction."

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   No    
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

**510(k) Number** K07507

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